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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/502,426 | 02/11/2000 | Ricardo Azpiroz | 11696-069001/2008-55300- | 5144 |

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EXAMINER

MEHTA, ASHWIN D

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/502,426 | Applicant(s) AZPIROZ ET AL. | |
| | Examiner Ashwin Mehta | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004 and 16 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-89,91-123 and 127-132 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 88 and 89 is/are allowed.
- 6) ☒ Claim(s) 58-61,63-70,72-79,82-87,91-123 and 127-132 is/are rejected.
- 7) ☒ Claim(s) 62,71 and 80 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. <u>08232004</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>09102004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 4, 2004 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 58-61, 63-70, 72-79, 82-87, 91-123, 125, and 127-132 under 35 U.S.C. 112, 1st paragraph, for containing new matter is withdrawn in light of Applicants' arguments. Note, however, that the claims remain rejected for lack of written description and scope of enablement as discussed below.

Claim Objections

4. Claims 62, 71, and 80 remain objected to for being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 112

5. Claims 58-61, 63-70, 72-79, 82-87, 91-123, and 127-132 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed February 4, 2004. Applicants traverse the rejection in the papers submitted August 4, 2004 and November 16, 2004. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that the claims recite a particular function and particular structures, and therefore have a combination of structural and functional characteristics. Applicants argue that this meets that standard of set forth in the decision of *Enzo Biochem, Inc. v. Gen-Probe, Inc.* (response filed August 4, 2004, pages 17-18, and November 16, 2004, pages 12-13). However, in the patent considered in that decision the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the case for the district court to make findings on whether there was a correlation between the structure of the deposited material and the function of variant material also claimed. As in *Enzo*, here the structure of nucleotide sequences encoding SEQ ID NO: 2 does not correspond exactly to the claimed polynucleotides. However, the functions of the claimed isolated polynucleotides have not been correlated to the variant structures encompassed by the claims.

Applicants argue that, with respect to structure, the specification provides support for the language appearing in the claims, that the specification states on page 18 that polynucleotides or polypeptides of the invention can demonstrate various percentage ranges of sequence identity,

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including 43%-60%, 60%-70%, 70-85%, 85-90%, 90-95%, and 95-98% sequence identity.

Applicants argue that specification on page 25 indicates that variants with one or more amino acid additions, substitutions and/or deletions, relative to the native molecule are included in the invention (response filed August 4, 2004, page 18; response filed November 16, 2004, page 13). However, the appearance of mere indistinct words does satisfy written description. Applicants also argue that domains of DWF4 characteristic of P450 proteins were also described (response filed November 16, 2004, page 13). However, as discussed in previous Office actions, numerous P450 proteins have these domains, but not the same functions. These domains in SEQ ID NO: 2 are not sufficient characteristics that can be coupled to the function of SEQ ID NO: 2, as they are present in proteins that have different functions.

Applicants also argue that the specification explicitly states that the various sequence identity value can be over a defined length of the molecules, which includes domains of SEQ ID NO: 2 (response submitted August 4, 2004, pages 18-19). However, the specification does not describe other amino acid sequences that will retain the functions of those domains. Applicants argue that *ipsis verbis* support for claim language is not required (response filed August 4, 2004, page 19). However, *Enzo Biochem. Inc. v. Genprobe Inc.*, 323 F.3d 1616 (Fed. Cir. 2002) teaches that the “appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement.”

In response to the issue that the specification does not describe amino acid sequences that differ from SEQ ID NO: 2 that would retain its functional activity, Applicants argue that the specification on pages 25-26 notes that DWF4 analogs refer to compounds having polypeptide structure with one or more amino acid substitutions, additions, and/or deletions, that the

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substitutions are preferably conservative in nature (response filed August 4, 2004, pages 19-20).

However, again, this is not a description of the amino acid sequences themselves. The specification does not describe a single species that has a structure that differs from nucleotide sequences that encode SEQ ID NO: 2, but whose product retains the same functional activity as SEQ ID NO: 2.

In response to issue that Nebert et al. (DNA and Cell Biology, Vol. 10, 1991) teaches that the P450 classification system was arbitrarily made, Applicants point to Nelson et al. (Pharmacogenetics, 1996, Vol. 6, pages 1-42) for indicating that though this classification of P450 genes was originally arbitrary, it turned out to be useful. Applicants argue that in view of this, one of ordinary skill in the art would know that this P450 classification system is useful (response filed November 16, 2004, pages 13-14). However, as discussed in the last Office action, Nelson et al. emphasize that similarities in enzymatic activities cannot be used to classify genes within any gene family or subfamily (page 4). Applicants argue that this passage from Nelson et al. goes on to discuss that a combination of structural and functional characteristics are generally useful in determining P450 nomenclature. Applicants argue that Nelson supports the conclusion that one of ordinary skill in the art would have recognized from the combination of structural and functional characteristics disclosed in the instant specification that polypeptides having greater than 43% identity to SEQ ID NO: 2 were described and invented by the present inventors (response filed November 16, 2004, page 14). However, the teaching in Nelson only refers to P450 nomenclature and classification. It does not teach that polypeptides having greater than 43% identity to a specific P450 would also have its functional activity.

Applicants also direct attention to a recent decision by the Board of Patent Appeals and Interferences (response filed November 16, 2004, pages 14-15). However, as recognized by Applicants, that was a non-precedential opinion and is non-binding to other applications.

6. Claims 58-61, 63-70, 72-79, 82-87, 91-123, and 127-132 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding SEQ ID NO: 2, plant host cells, transgenic plants comprising a polynucleotide encoding SEQ ID NO: 2, method of making a transgenic plant comprising introducing into a plant a polynucleotide encoding SEQ ID NO: 2, and a method for producing a polypeptide in plant cell comprising providing a plant host cell comprising introducing a polynucleotide encoding SEQ ID NO: 2, does not reasonably provide enablement for polynucleotides that do not encode SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed February 4, 2004. Applicants traverse the rejection in the papers submitted August 4, 2004 and November 16, 2004. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that the specification points out particular replacements that may not have a major effect on desired biological activity, including leucine with isoleucine or valine, aspartate with glutamate; and threonine with serine. Applicants argue that the specification provides guidance as to conserved amino acid residues within domains and anchor and proline-rich regions of 22 α -hydroxylase, and guidance on how to measure 22 α -hydroxylase activity

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(response filed November 16, 2004, page 16 and August 4, 2004, pages 21-22). However, the discussion of conserved amino acid changes in the specification is general, and does not indicate that any such changes actually do result in a protein in which 22 α -hydroxylase activity was retained. Further, the claims are not limited to any particular type of amino acid changes in the polypeptide encoded by the polynucleotide. Further, the domains of DWF4 are also present in P450 proteins that do not have 22 α -hydroxylase activity. Applicants argue that every last detail need not be described (response filed August 4, 2004, page 22). However, not a single polynucleotide encoding a polypeptide that differs from SEQ ID NO: 2 but that retains its functional activity is taught.

Summary

7. Claims 88 and 89 are allowed. Claims 62, 71, and 80 are objected. Claims 58-61, 63-70, 72-79, 82-87, 91-123, and 127-132 are rejected.

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

January 27, 2005



Ashwin D. Mehta, Ph.D.
Primary Examiner
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